The FloTrac System 4.0

Continuously Evolving to Meet Your Clinical Needs

The Latest Evolution of the FloTrac System Algorithm Provides Increased Reliability Under More Clinical Conditions

Expanded Patient Data

- The FloTrac system algorithm has been updated to include more diverse clinical situations and procedures such as: gastrointestinal, pancreaticoduodenectomy (whipple), kidney transplant, nephrectomy, hip replacement and esophagectomy

Cardiac Output / Stroke Volume – Tracks More Closely with Changes in Physiology

- Cardiac Output (CO) tracks more closely with patient physiology in transient clinical situations where a rapid change in afterload occurs (for example, following a bolus of vasopressors)

Stroke Volume Variation – Reliably Use SVV in Expanded Situations

- Monitor and utilize Stroke Volume Variation in most patients despite significant arrhythmias

I. Algorithm Overview

Trusted by more clinicians and used on over 1 million patients worldwide, the FloTrac system from Edwards Lifesciences provides real-time measurement of advanced hemodynamic parameters, such as Continuous Cardiac Output (CCO), Stroke Volume (SV), Stroke Volume Variation (SVV), and Systemic Vascular Resistance (SVR) through an existing arterial line. The system is operator independent, reliable and minimally invasive and may be used to hemodynamically optimize moderate to high-risk surgical and critically ill patients. Flow-based parameters, such as Stroke Volume are calculated every 20 seconds based on patient arterial pressure data obtained using the FloTrac sensor, along with patient demographics. The system continuously monitors changes in vascular tone (compliance and resistance) and automatically adjusts, eliminating the need for manual calibration.

II. The FloTrac System Algorithm Development and Evolution

The FloTrac system is powered by the evolving FloTrac system algorithm, which was developed based on cardiovascular hemodynamic principles, advanced signal processing of the arterial pressure waveform, and comparative analysis with the clinical gold standard, thermodilution Cardiac Output. The algorithm was modeled and compared across a wide range of hemodynamic values, patient profiles, pathologies, and hemodynamic conditions.

III. Arterial Pressure-Based Cardiac Output (APCO) and Stroke Volume

Cardiac Output is an important component of global oxygen delivery and is the variable most often manipulated to improve oxygen delivery. Cardiac Output is calculated by multiplying heart rate by Stroke Volume (CO = HR x SV). The FloTrac system algorithm uses similar components but substitutes heart rate with Pulse Rate (PR), capturing only truly perfused beats, and multiplies Pulse Rate by a calculated Stroke Volume. The FloTrac system algorithm analyzes the arterial pressure waveform at one hundred times per second over 20 seconds, capturing 2,000 data points for analysis. These data points are used, along with patient demographic information, to calculate the standard deviation of the arterial pressure, which is multiplied by a conversion factor that incorporates the effects of resistance and compliance.

The FloTrac System Cardiac Output

Formula for Cardiac Output = Heart Rate x Stroke Volume

The FloTrac System Cardiac Output = Pulse Rate x [std(BP)*χ]

Pulse Rate (PR)
- Measured as beats per minute
- Beats identified by upslope of waveforms
- Advanced beat detection differentiates fully perfused beats
- Computed from 20-second time period of beats

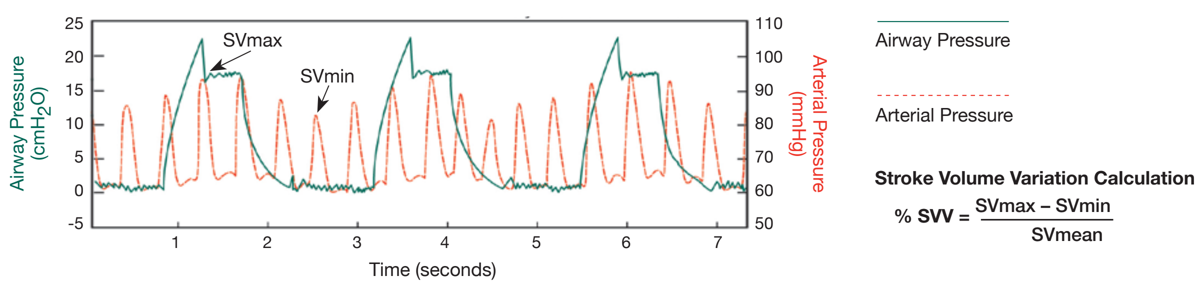
Standard deviation of arterial Blood Pressure [std(BP)]
- Pulse pressure ∞ SV ∞ std(BP)
- Measured as mmHg
- Computed on a beat-by-beat basis

The x factor compensates for differences in vascular compliance and resistance
- Patient-to-patient differences estimated from biometric data
- Dynamic changes estimated by waveform analysis (skewness, kurtosis of the waveform)
- Measured as mL per beat/mmHg
- 20 second average updates

IV. Stroke Volume Variation

Traditional hemodynamic monitoring parameters (HR, MAP, CVP, and PAOP) are often insensitive and sometimes misleading in the assessment of circulating blood volume. Stroke Volume Variation has been shown to have a high sensitivity and specificity compared with conventional indicators of volume status and their ability to determine fluid responsiveness.[1-3] Optimization of intravascular volume based on real-time changes in Stroke Volume Variation may be an appropriate strategy for patients in whom tighter control of fluid replacement is beneficial.

Figure 1: Stroke Volume Variation and Fluid Optimization
On Control Ventilated Patients[4]



Stroke Volume Variation – Several Requirements[4]

Although a powerful tool in managing patients' volume administration, Stroke Volume Variation has several limitations, including:

- **100% Mechanical ventilation** – Currently, literature supports the use of Stroke Volume Variation only on patients who are 100% mechanically (control mode) ventilated with tidal volumes of more than 8 cc/kg and fixed respiratory rates (see Figure 1)
- **Spontaneous breathing** – The literature does not support the use of Stroke Volume Variation with patients who are spontaneously breathing due to the irregular nature of rate and tidal volumes
- **Severe arrhythmias** – Atrial fibrillation can dramatically affect Stroke Volume Variation values due to the severe irregular rhythm. For this reason the use of Stroke Volume Variation as a guide for volume resuscitation is not recommended in patients with atrial fibrillation

Note: Limitations associated with SVV are not limitations of the FloTrac system in calculating CO or SV.

V. The FloTrac System 4.0

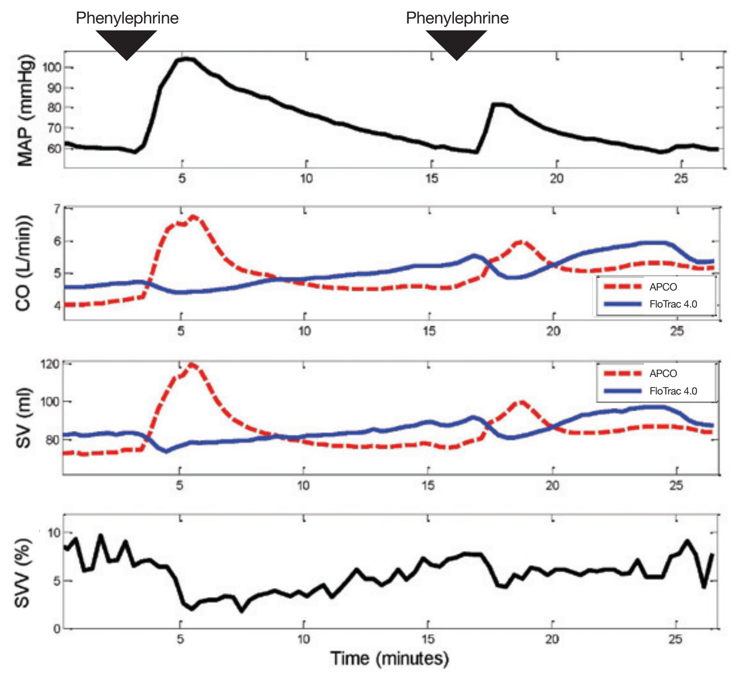
Expanded Patient Data

The FloTrac system algorithm has evolved based on a broad and expanding patient database that allows ongoing system performance improvements. In this latest evolution (v.4.0), Edwards continues to expand the database to include a more diverse surgical patient population in order to continuously inform and evolve the algorithm. Specifically, more of the following high-risk surgical patients were added to the database including, but not limited to gastrointestinal, pancreaticoduodenectomy (whipple), kidney transplant, nephrectomy, hip replacement and esophagectomy. The expanded patient database has informed the algorithm to recognize and adjust for more patient conditions. As a result, the FloTrac system and the sophisticated FloTrac system algorithm provide insight that allows clinicians to make critical decisions earlier and more effectively than for patients monitored with vital signs alone.

The FloTrac System 4.0 Algorithm Tracks Patient Physiology More Closely

In this latest evolution, Cardiac Output better tracks with transient patient physiology in clinical situations where a rapid change in afterload occurs, for example, after a bolus infusion of vasopressors (see Figure 2).[5]

Figure 2: The FloTrac System 4.0 Algorithm vs. APCO

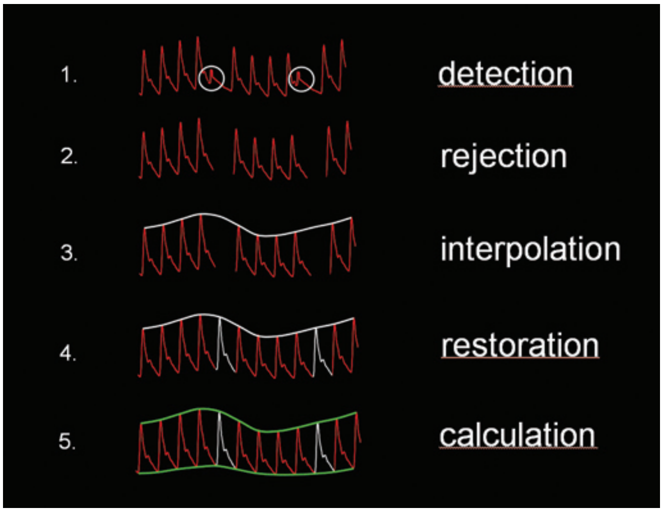


The FloTrac System SVV Enhancement

The FloTrac system algorithm, through its continuous beat detection and analysis, allows for the ongoing use of Stroke Volume Variation as a reliable indicator of preload responsiveness. The FloTrac system algorithm enables the display and use of Stroke Volume Variation even in patients with multiple premature atrial or ventricular contractions (PACs and PVCs). Specifically, the FloTrac system allows the physician to guide volume resuscitation despite most arrhythmias (see Figure 3).

At least eight clinical studies published in leading medical journals have validated $SVV_{FloTrac}$ as an accurate predictor of preload responsiveness.[2,6-14] And Benes and Cecconi have demonstrated that a peripoerative goal-directed therapy strategy based on optimization of Stroke Volume Variation and cardiac output can improve patient outcomes.[15,16]

Figure 3: Estimation of Stroke Volume Variation by the SVVxtra algorithm is based on detection of abnormal beats, rejection of abnormal beats, interpolation of remaining beats, restoration of missing beats, and calculation of Stroke Volume Variation[17]



Greater Insight for Clinical Decisions

The key hemodynamic parameters provided by the FloTrac system give greater clarity when making clinical decisions to ensure the appropriateness of interventions and avoid the harmful effects of excessive, insufficient, and inappropriate volume administration.[18,19] Providing volume administration in the optimal range is important because both hypo- and hypervolemia may deleteriously affect organ function. Hemodynamic optimization through the use of protocols, such as Perioperative Goal-Directed Therapy (PGDT), which include these advanced hemodynamic parameters, can ensure the patient is maintained in the optimal range.[18] This updated algorithm provides a more reliable solution for use in PGDT protocols in more surgical procedures and patient types.

Edwards has changed the complexity and invasiveness traditionally associated with continuous hemodynamic monitoring into the simplicity of utilizing only an arterial catheter. The ease of use and reliability of the FloTrac system in moderate to high-risk surgical and critically ill patients provides clinicians the option to monitor Cardiac Output, Stroke Volume Variation, Stroke Volume and other key hemodynamic parameters on any patient who requires an arterial line.

This latest evolution of the FloTrac system algorithm provides increased reliability under more clinical conditions and is an example of how Edwards strives to continuously engage with clinicians to understand and meet expanding clinical needs.

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